

**REMARKS/ARGUMENTS**

The Examiner rejected claims 17 “under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which application regards as the invention.” In particular, the Examiner objected to the use of the term “such as” in line 4 of the claim. By this amendment, applicant has amended claim 17 to overcome the indefiniteness rejection.

The Examiner rejected claims 1 and 2 “under 35 U.S.C. 102(b) as being anticipated by Castaldi (5031638).”

Applicant has amended independent claim 1 to more particularly point out the patentably novel features of this invention and to clearly distinguish the claimed oral appliance over the disclosure in the Castaldi ‘638 patent.

Claim 1 has been amended to make it clear that the base member is made from a plastic material which is rigid and non-thermoplastic at a temperature of 90 – 95°C. Moreover, claim 1 also specifies that “a continuous layer of thermoplastic material that encompasses the base member ... firmly and securely mount[s] the layer of thermoplastic material on the base member, the layer of thermoplastic material forming teeth engaging elements which can be conformed or moulded to suit the individual teeth of a user by heating to a temperature at which the layer is plastic and formable.

The Castaldi ‘638 patent simply does not disclose or render obvious the subject matter specified in independent claim 1.

Castaldi discloses an oral appliance wherein the base member or core layer, as well as the inner and outer layers, are made out of ethylene/vinyl acetate copolymer. The only difference between the ethylene/vinyl acetate copolymer of the base member and the ethylene/vinyl acetate copolymer employed in the inner and outer layers is that the inner and outer layers are conformable at a temperature of 100 – 120°F (37.78°C – 48.89°C) and the core layer softens at a temperature of about 160°F and below 200°F (71°C – 93°C). Thus, the core layer is formed of an EVA copolymer that is designed to soften below the boiling point of water, e.g., about 95°C. The functional reason for this is so that the base can be softened by immersing it in boiling water and as a result the appliance can be widened or narrowed to accommodate different arch widths. This is a major distinction from applicant's invention as specified in claim 1; namely, that the plastics material of applicant's core layer is rigid and non-thermoplastic at a temperature of 90 – 95°C. If the base were not capable of being so manipulated in the Castaldi construction it would not be possible for a user to alter the arch width of the appliance. In other words, it would not be possible to perform its intended purpose of being customizable to fit most users.

Thus, the Castaldi '638 patent teaches the use of the same EVA thermoplastic material for both the base and the inner and outer layers. Moreover, to enable the appliance to be adapted to accommodate users with different arch widths, the EVA of the base member must be thermoplastic at a temperature of 95°C. Therefore, it does not remain hard and rigid when placed in boiling water.

In distinction to the disclosed construction in the Castaldi '638 patent, claim 1 has been amended to make it clear that the base member in applicant's construction is non-thermoplastic

at a temperature of 90 – 95°C. Thus, when applicant's appliance is placed in boiling water, the core member will remain hard and rigid, which is directly contrary to the construction disclosed in the Castaldi '638 patent.

Thus, the Castaldi '638 patent actually teaches away from the invention specified in claim 1, particularly as amended herein.

A further problem that exists when forming an oral appliance as a multi-layer structure is that the different layers tend to delaminate from each other. Often the materials employed to make such a structure do not bond to each other to a sufficient extent to avoid such delamination. In addition, during use the materials are subjected to heating and cooling and the associated expansion and contraction that results from such changes in temperature. Moreover, during use the materials are required to flex, and again this involves extension and contraction of the layers, which often can cause delamination.

Consequently, the teachings in the Castaldi '638 patent, which represented the conventional thinking in the prior art at the time applicant's invention was made, discloses that the best way to resist the problem of delamination is to form all of the layers out of the same material. Specifically, it was believed that EVA would only be able to bond to and be sufficiently compatible with another layer of EVA. This explains why Castaldi used EVA for both the core and inner and outer layers. Other inventors in the field at the same time, including Adell, were doing the same thing. None of the prior art references suggest or contemplate moving outside of this paradigm.

Castaldi sought to achieve his objective of conferring rigidity to the core by selecting an EVA for the base material that is not thermoplastic at the same temperatures that the inner and outer layers are thermoplastic. However, Castaldi was constrained by the fact that he believed that he had to stick with an EVA material for the core and never suggested or considered the possibility of using a different material. A strong theme in the design of the Castaldi et al. oral appliance is that all layers be made of the same basic material, principally to resist delamination.

In addition to the fact that Castaldi's core material had to be made of EVA, it also had to be made out of a material that was thermoplastic at less than 100°C to achieve the functional requirement that the arch width could be adjusted after it was dipped in boiling water. Thus, even though the core remains rigid at the temperature that the inner and outer layers soften, it was required to be thermoplastic when placed in boiling water.

As noted above, in distinction to the teachings in the Castaldi patent, the core material in applicant's invention is required to be non-thermoplastic at a temperature of 90 – 95°C.

A further distinction between the structure disclosed in the Castaldi '638 patent and the oral appliance specified in claim 1, is that the inner and outer layers employed in the Castaldi construction are formed as separate layers that are contiguous to each other. Castaldi only envisaged that the inner and outer layers be formed as two separate layers in separate injection moulding operations. Castaldi et al. does not remotely suggest forming the inner and outer layers as "a continuous layer ... that encompasses the base member" as specified in claim 1. This further reinforces applicant's position that Castaldi never contemplated using anything other than EVA for the base member. Moreover, if another material had been used for the base

member in the Castaldi construction, the inner and outer layers would have been highly susceptible to delaminating from the base member, by virtue of being formed as separate layers.

By virtue of Castaldi employing the identified EVA as the core layer, the Castaldi appliance has limited strength and rigidity. Although this latter appliance is capable of some bending and flexing, it will not be as hard and rigid as an appliance made from some of the engineering plastics materials. Moreover, although the EVA material employed by Castaldi in the core is not thermoplastic at 100° – 120° Fahrenheit (38°C – 49°C) it is thermoplastic when placed in boiling water and will soften and lose its shape when so heated. This is in distinction to applicant's construction, which does not become thermoplastic in boiling water.

It is not a simple matter to simply experiment with other materials for use in the core. In particular, use of other materials for the core to make it more rigid would make the appliance more prone to delamination. This is because the inner and outer layers are separate from each other and there is no mechanical encasement to hold them together and to the core.

Thus, as noted above, the notion of laminating only like plastics materials with each other was the conventional thinking at the time that applicant conceived of his invention. Prior references of which the applicant has knowledge taught towards the use of the same material, namely, EVA, for all of the layers of the appliance.

However, applicant did not believe that any of the products in the prior art were satisfactory, and, at least, there was definitely a need for an improved product. In fact, even though the same materials were being employed for the different layers in the prior art structures,

they still tended to delaminate. Applicant had significant concerns that the base members of the guards were not sufficiently rigid for the intended use of the product.

Based upon applicant's concern he conceived that a completely different approach from the prior art was needed. Thus, applicant took a completely different direction from the teachings in the Castaldi patent, as well as from the conventional thinking in the field.

Applicant's invention is predicated, in part, on his refusal to accept the fundamental premise in the prior art that all of the layers of the appliance must be of EVA material, in order for the appliance to resist delamination. Applicant discovered that the use of other materials in the core, and in particular the engineering plastics, were much stronger and rigid, and also non-thermoplastic over the temperature range of application of the invention, namely 20° – 100°C. Thus, the engineering plastics employed in applicant's invention did not become plastic and formable in boiling water. They would have to be heated well above the temperature of boiling water before they soften and become thermoplastic and formable. Typically they would only soften well above 150°C.

In spite of applicant's recognition of the above-identified advantages of strength and rigidity from using an engineering plastics material, applicant still needed to resolve the problem of delamination of the EVA layer from the base member. This delamination problem became more severe when considering the use of a different material for the core member. Applicant ultimately came up with the idea of having the outer layer in the form of a continuous layer of thermoplastic material that encased the base member. This mechanical encasement of the base member was determined to hold the EVA tightly over the base member and reduce the

propensity for it to delaminate, irrespective of the compatibility of the materials. Thus, a significant feature of the present invention is that the EVA layer is in the form of a continuous layer that encases the base member. In accordance with this invention the outer layer is not made of two or more side by side contiguous layers, as is disclosed in the Castaldi patent.

As a result of applicant's inventive activity, he determined that a number of rigid engineering plastic materials, and most desirable polypropylene, polyurethane and santoprine were very compatible with EVA. The EVA layer did not tend to delaminate from a base member formed of these latter rigid plastic materials when applied as a continuous layer, even when the appliance was subjected to the rigors of heating and cooling as well as flexing of the appliance.

Claim 17, which is dependent upon claim 1, specifies that the face member is made from a polymer selected from the group consisting of polyurethane, polypropylene and santoprine.

In order to improve the versatility of the product, applicant needed to deal with the issue of constructing the mouth guard so that it could accommodate, or be adjusted to accommodate, users having different arch widths. This posed an additional problem because the desired plastics material for the core member did not soften — and indeed were not intended to soften — when placed in boiling water.

Adjustability is a very desirable feature of the oral appliance, particularly if the oral appliance is intended to meet its objective of being a one-size-fits-all product. Applicant determined that providing a groove or notch adjacent the upper surface of the front flange enabled the U-shaped appliance to be widened and narrowed to thereby accommodate different arch widths without softening the base member. The inclusion of such a notch has enabled

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applicant to use rigid engineering plastics material for the base member while still enabling the arch width to be adjusted. The inclusion of a notch in the appliance of this invention is specified in claim 19, which is dependent upon independent claim 1.

In summary, significant features that distinguish the appliance of the present invention over the prior art are that a thermoplastic material such as EVA forms a continuous layer that encases the base member to hold the EVA layer to the base member and resists delamination. In addition, the applicant has gone against conventional wisdom by choosing a plastics material for the core member that is not thermoplastic in the temperature range of boiling water, and is therefore not EVA. Applicant has established that such materials are sufficiently compatible with the EVA such that when they are encased in the EVA they resist delamination in use.

Thus, applicant has successfully invented an oral appliance that can be custom fitted by a user, that is stronger and more rigid than the prior art structures, and that also resists delamination. This surprising and unexpected result has never been suggested by anyone else prior to the present invention.

The Examiner apparently recognized a number of the benefits discussed above when he allowed the application that issued into U.S. Patent No. 6,637,436. This latter patent covers a species of an oral appliance that, like the present invention, employs a base member made of a different material than the outer layer and wherein the outer layer is a continuous layer of an EVA material that surrounds and encases the base member.

In the most recent Office Action the Examiner raised a double-patenting rejection against the presently pending claims in this application. Enclosed with this Amendment is a Terminal Disclaimer, which obviates the double-patenting rejection.

Turning now to the remaining dependent claims, claim 2 is dependent upon claim 1 and specifies that the base member defines an upper channel within which the upper row of teeth of a user is received. This feature in combination with the features of parent claim 1 is neither shown nor suggested in the prior art of record and therefore claim 2 is submitted to be patentable thereover.

Claim 3 is dependent upon claim 1 and specifies that the base member defines both upper and lower channels within which respectively the upper and lower rows of teeth of a user are received. This feature in combination with the features specified in claim 1 is neither shown nor suggested in the prior art of record and therefore claim 3 is submitted to be patentable thereover.

Claim 17 is dependent upon claim 1 and specifies that the continuous layer of thermoplastic material is EVA and softens at a temperature of 90°C – 95°C, and that the base is made out of a polymer from the group consisting of polyurethane, polypropylene and santoprine. The features specified in claim 17, either alone or in combination with the features of parent claim 1 are neither shown nor suggested in the prior art of record and therefore claim 17 is submitted to be patentable thereover.

Claim 18 is dependent upon claim 1 and specifies that the continuous layer of thermoplastic material forming the teeth engaging elements have a thickness of 1mm – 3mm and wherein the continuous layer of thermoplastics material substantially covers the full surface area

of the base member. The features specified in claim 18, either alone or in combination with the features specified in parent claim 1 are neither shown nor suggested in the prior art of record and therefore claim 18 is submitted to be patentable thereover.

Claim 19 is dependent upon claim 1 and specifies that the appliance includes a tongue tag formed on the inner flange of the base member and that the appliance further includes breathing apertures for facilitating breathing by a user when wearing the appliance. In addition claim 19 specifies the presence of a notch in an upper surface of the outer flange for permitting inward and outward adjustment of the U-shaped member. The features specified in claim 19, either alone or in combination with the features specified in parent claim 1 are neither shown nor suggested in the prior art of record and therefore claim 19 is submitted to be patentable thereover.

Claim 20 is an independent method claim that essentially parallels the features of article claim 1. In particular, claim 20 clearly specifies that the base member is first moulded from a plastic material in a first moulding step, and that this plastics material is rigid and non-thermoplastic at a temperature of 90 – 95°C. Claim 20 goes on to specify that the base member is then removed from the first mould and placed in a second mould having a larger mould cavity and then moulding a continuous layer of thermoplastic material onto the base member to form upper and lower teeth engaging elements that are capable of being customized to suit the mouth of a user. For the various reasons discussed early, which will not be repeated herein for purposes of brevity, claim 20 is submitted to set forth patentably novel subject matter.

Claim 21 is dependent upon claim 20 and specifies that the moulded base member defines an upper channel within which the upper row of teeth of a user is received or alternatively that the base member defines both upper and lower channels within which respectively the upper and lower rows of teeth of a user are received. The features specified in claim 21 in combination with the features in parent claim 20 are neither shown nor suggested in the prior art of record and therefore claim 21 is submitted to be patentable thereover.

Claim 22 is dependent upon claim 20 and specifies that the continuous layer of thermoplastic material is moulded substantially fully across the surface area of the base member in the second moulding step and also that the layer of thermoplastic material is injection moulded from EVA while it is locked in position in the second mould. The features specified in claim 22 in combination with the features specified in parent claim 20 are neither shown nor suggested in the prior art of record and therefore claim 22 is submitted to be patentable thereover.

Claim 23 is dependent upon claim 20 and specifies that the base member is injection moulded from a polymer from the group consisting of polyurethane, polypropylene or santoprine. This feature in combination with the features specified in parent claim 20 are neither shown nor suggested in the prior art of record and therefore claim 23 is submitted to be patentable thereover.

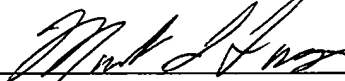
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In view of the above remarks, applicant submits that all of the claims presented for consideration herein set forth patentably novel subject matter, and therefore an indication to that effect is respectfully requested.

Respectfully submitted,

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